

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization

International Bureau



(10) International Publication Number

WO 2013/016240 A1

(43) International Publication Date
31 January 2013 (31.01.2013)

WIPO | PCT

(51) International Patent Classification:
A61M 1/00 (2006.01) *A61F 15/02* (2006.01)

(74) Agents: **WELCH, Gerald, T.** et al.; SNR Denton US LLP, P.O.Box 061080, Wacker Drive Station, Willis Tower, Chicago, IL 60606 (US).

(21) International Application Number:

PCT/US2012/047736

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(22) International Filing Date:
20 July 2012 (20.07.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/511,827 26 July 2011 (26.07.2011) US
61/511,840 26 July 2011 (26.07.2011) US

(71) Applicant (for all designated States except US): **KCI LICENSING, INC.** [US/US]; Legal Department - Intellectual Property, P.O. Box 659508, San Antonio, TX 78265-9508 (US).

(72) Inventors; and

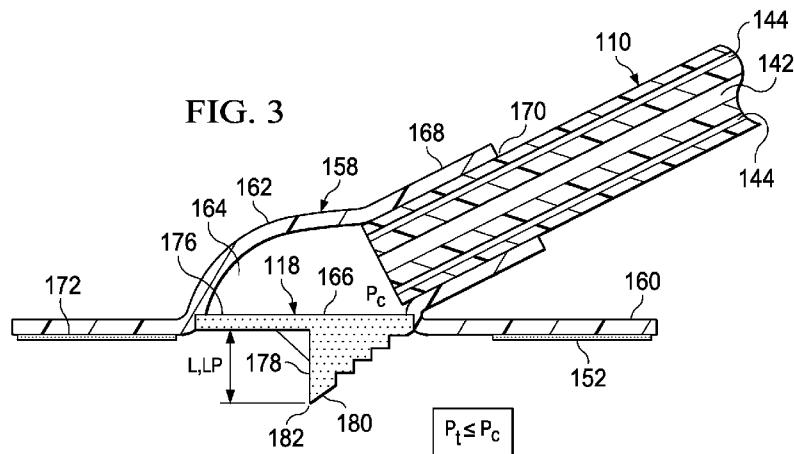
(75) Inventors/Applicants (for US only): **TOUT, Aidan, Marcus** [GB/GB]; 9 Collingwood Close, Alderbury, Wiltshire SP5 3FE (GB). **LOCKE, Christopher, Brian** [GB/GB]; 6 Bosworth Mews, Bournemouth, Dorset BH9 3SD (GB). **ROBINSON, Timothy, Mark** [GB/GB]; 27 Wellington Terrace, Basingstoke, Hampshire RG23 8HH (GB).

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: SYSTEMS AND METHODS FOR TREATING A TISSUE SITE WITH REDUCED PRESSURE INVOLVING A REDUCED-PRESSURE INTERFACE HAVING A CUTTING ELEMENT



(57) Abstract: Systems and methods for a reduced-pressure interface for providing reduced pressure through a sealing member to a distribution manifold includes a housing having a flange portion and a cavity wall portion such that the cavity wall portion forms a cavity having a tissue-facing cavity opening. A conduit port is coupled to the cavity wall and has a conduit aperture, such that the conduit port is adapted to receive a reduced-pressure delivery conduit. An attachment device is coupled to a tissue-facing side of the flange portion of the housing such that the attachment device couples the housing to the sealing member. Additionally, a cutting element is at least temporarily coupled to the housing proximate to the tissue-facing cavity opening such that the cutting element is adapted to form an aperture in the sealing member when the cutting element is driven into the sealing member with a driving force.

WO 2013/016240 A1

SYSTEMS AND METHODS FOR TREATING A TISSUE SITE WITH REDUCED PRESSURE INVOLVING A REDUCED-PRESSURE INTERFACE HAVING A CUTTING ELEMENT

5

RELATED APPLICATIONS

[0001] The present invention claims the benefit, under 35 USC § 119(e), of the filing of U.S. Provisional Patent Application serial number 61/511,840, entitled “Systems and Methods for Treating a Tissue Site with Reduced Pressure Involving a Reduced-Pressure Interface having a Cutting Element,” filed July 26, 2011, and U.S. Provisional Patent 10 Application serial number 61/511,827, entitled “Systems and Methods for Treating a Tissue Site with Reduced Pressure Involving a Reduced-Pressure Interface having a Multi-Lumen Conduit for Contacting a Manifold,” filed July 26, 2011, which is incorporated herein by reference for all purposes.

BACKGROUND

15 [0002] The present disclosure relates generally to medical treatment systems and, more particularly, but not by way of limitation, to systems, methods, and apparatuses for treating a tissue site with reduced pressure involving a reduced-pressure interface having a cutting element.

20 [0003] Clinical studies and practice have shown that providing a reduced pressure in proximity to a tissue site augments and accelerates the growth of new tissue at the tissue site. The applications of this phenomenon are numerous, but application of reduced pressure has been particularly successful in treating wounds. This treatment (frequently referred to in the medical community as “negative pressure wound therapy,” “reduced pressure therapy,” or “vacuum therapy”) provides a number of benefits, which may include faster healing and 25 increased formulation of granulation tissue. Typically, reduced pressure is applied to tissue through a manifold device. The porous pad contains cells or pores distributes reduced pressure to the tissue and channel fluids that are drawn from the tissue.

SUMMARY

[0004] According to an illustrative embodiment a reduced-pressure interface for providing reduced pressure through a sealing member to a distribution manifold includes a housing having a flange portion and a cavity wall portion such that the cavity wall portion forms a cavity having a tissue-facing cavity opening. A conduit port is coupled to the cavity wall and has a conduit aperture, such that the conduit port is adapted to receive a reduced-pressure delivery conduit. An attachment device is coupled to a tissue-facing side of the flange portion of the housing such that the attachment device couples the housing to the sealing member. Additionally, a cutting element is at least temporarily coupled to the housing proximate to the tissue-facing cavity opening such that the cutting element is adapted to form an aperture in the sealing member when the cutting element is driven into the sealing member with a driving force.

[0005] According to another illustrative embodiment a system for treating a tissue site on a patient with reduced pressure includes a distribution manifold for placing proximate to the tissue site, a sealing member for covering the distribution manifold and a portion of intact epidermis of the patient to form a sealed space, a reduced-pressure interface for providing reduced pressure through the sealing member to the distribution manifold, a reduced-pressure source, and a reduced-pressure delivery conduit for fluidly coupling the reduced-pressure source to the reduced-pressure interface. The reduced-pressure interface includes a housing having a flange portion and a cavity wall portion such that the cavity wall portion forms a cavity having a tissue-facing cavity opening, a conduit port coupled to the cavity wall and having a conduit aperture such that the conduit port is adapted to receive the reduced-pressure delivery conduit, an attachment device coupled to a tissue-facing side of the flange portion of the housing such that the attachment device couples the housing to the sealing member, and a cutting element at least temporarily coupled to the housing proximate to the tissue-facing cavity opening. The cutting element is adapted to form an aperture in the sealing member when the cutting element is driven into the sealing member with a driving force.

[0006] According to another illustrative embodiment a method for treating a tissue site on a patient with reduced pressure includes disposing a distribution manifold proximate to the tissue site and covering the distribution manifold and a portion of intact epidermis of the patient with a sealing member to form a sealed space in which the distribution manifold is disposed. The sealing member has a first side and a second, tissue-facing side. The method further includes providing a reduced-pressure source, coupling a reduced-pressure interface

proximate to the first side of the sealing member, and fluidly coupling a reduced-pressure delivery conduit between the reduced pressure source and the reduced-pressure interface. The reduced-pressure interface includes a housing having a wall portion such that the wall portion forms a cavity having a tissue-facing cavity opening, a conduit port coupled to the cavity wall 5 for receiving the reduced-pressure delivery conduit, an attachment device for coupling the reduced-pressure interface to the sealing member, and a cutting element at least temporarily coupled to the housing proximate to the tissue-facing cavity opening such that the cutting element is adapted to perforate the sealing member when the cutting element is driven into the sealing member with a driving force. The method also includes applying a driving force to the 10 reduced-pressure interface of sufficient strength to cause the cutting element to perforate the sealing member.

[0007] According to yet another illustrative embodiment, an interface for providing reduced pressure through a drape to a manifold includes a housing having a flange portion and a cavity wall portion. The cavity wall portion forms a cavity and a cavity wall aperture is 15 formed within the cavity wall portion for receiving a tube. The interface further includes a coupler positioned on a tissue-facing side of the flange portion of the housing for attaching the housing to the drape and a protrusion coupled to the housing proximate to the flange portion. The protrusion extends beyond the tissue-facing side of the flange portion of the housing and is configured to form an aperture in the drape when the protrusion is driven into the drape with 20 the reduced pressure.

[0008] According to another illustrative embodiment, a system for treating a wound with reduced pressure includes a manifold for positioning adjacent the wound, a drape for covering the manifold and a portion of intact epidermis of the patient to form a sealed space, a reduced-pressure interface for providing reduced pressure through the drape to the manifold, a 25 reduced-pressure source, and a conduit for fluidly coupling the reduced-pressure source to the reduced-pressure interface. The reduced-pressure interface includes a housing having a flange portion and a cavity wall portion. The cavity wall portion forms a cavity and a cavity wall aperture is formed within the cavity wall portion for receiving a tube. The reduced-pressure interface further includes a coupler positioned on a tissue-facing side of the flange portion of the housing for attaching the housing to the drape and a protrusion coupled to the housing proximate to the flange portion. The protrusion extends beyond the tissue-facing side of the flange portion of the housing and is configured to form an aperture in the drape when the protrusion is driven into the drape with 30 the reduced pressure.

[0009] In another illustrative embodiment, a method for treating a wound on a patient with reduced pressure includes disposing a manifold proximate to the wound, covering the manifold and a portion of intact epidermis of the patient with a drape to form a sealed space in which the manifold is disposed. The drape has a first side and a second, tissue-facing side.

- 5 The method further includes providing a reduced-pressure source, coupling a reduced-pressure interface proximate to the first side of the drape, and fluidly coupling a tube between the reduced-pressure source and the reduced-pressure interface. The reduced-pressure interface includes a housing having a flange portion and a cavity wall portion. The cavity wall portion forms a cavity and a cavity wall aperture is formed within the cavity wall portion for receiving a tube. The reduced-pressure interface further includes a coupler positioned on a tissue-facing side of the flange portion of the housing for attaching the housing to the drape and a protrusion coupled to the housing proximate to the flange portion. The protrusion extends beyond the tissue-facing side of the flange portion of the housing and is configured to form an aperture in the drape when the protrusion is driven into the drape with a driving force. The method
- 10 further includes applying the driving force to the reduced-pressure interface of sufficient strength to cause the protrusion to perforate the drape.
- 15

[0010] Other features and advantages of the illustrative embodiments will become apparent with reference to the drawings and detailed description that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIGURE 1 is a schematic perspective view of an illustrative embodiment of a system for treating a tissue site with reduced pressure;

5 [0012] FIGURE 2 is a schematic, cross-sectional view of an illustrative embodiment of a multi-lumen conduit of the system shown in FIGURE 1 taken along line 2-2;

[0013] FIGURE 3 is a schematic, cross-sectional view of one illustrative embodiment of a reduced-pressure interface having a cutting element for use as part of a system for treating a tissue site with reduced pressure;

10 [0014] FIGURE 4 is a schematic, bottom view of the reduced-pressure interface of FIGURE 3;

[0015] FIGURE 5A is a schematic, cross-sectional view of the reduced-pressure interface of FIGURE 3 under reduced pressure prior to the cutting element perforating a sealing member;

15 [0016] FIGURE 5B is another schematic, cross-sectional view of the reduced-pressure interface of FIGURE 3 under reduced pressure after the cutting member has perforated the sealing member;

[0017] FIGURE 5C is another schematic, cross-sectional view of the reduced-pressure interface of FIGURE 3 under reduced pressure after the cutting member has perforated the sealing member and the cutting element has been removed;

20 [0018] FIGURE 6 is a schematic, top perspective view of another illustrative embodiment of a reduced-pressure interface having a cutting element for use as part of a system for treating a tissue site with reduced pressure;

[0019] FIGURE 7 is a schematic, cross-sectional view of the reduced-pressure interface of FIGURE 6;

25 [0020] FIGURE 8 is a schematic, bottom perspective view of a portion of the reduced-pressure interface of FIGURE 6;

[0021] FIGURE 9A is a schematic, cross-sectional view of the reduced-pressure interface of FIGURES 6-8 being applied and prior to reduced pressure being supplied;

30 [0022] FIGURE 9B is a schematic, cross-sectional view of the reduced-pressure interface of FIGURES 6-8 under reduced pressure prior to the cutting element perforating a sealing member;

[0023] FIGURE 9C is a schematic, cross-sectional view of the reduced-pressure interface of FIGURES 6-8 under reduced pressure after the cutting member has perforated the sealing member and the cutting element has been removed; and

[0024] FIGURE 10 is a schematic diagram of a representative pressure set-up pattern.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0025] In the following detailed description of the illustrative embodiments, reference is made to the accompanying drawings that form a part hereof. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is understood that other embodiments may be utilized and that logical structural, mechanical, electrical, and chemical changes may be made without departing from the spirit or scope of the invention. To avoid detail not necessary to enable those skilled in the art to practice the embodiments described herein, the description may omit certain information known to those skilled in the art. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the illustrative embodiments are defined only by the appended claims. Unless otherwise indicated, as used herein, “or” does not require mutual exclusivity.

[0026] The term “reduced pressure” as used herein generally refers to a pressure less than the ambient pressure at a tissue site that is being subjected to treatment. In most cases, this reduced pressure will be less than the atmospheric pressure at which the patient is located. Alternatively, the reduced pressure may be less than a hydrostatic pressure associated with tissue at the tissue site. Unless otherwise indicated, values of pressure stated herein are gauge pressures. References to increases in reduced pressure typically refer to a decrease in absolute pressure, and decreases in reduced pressure typically refer to an increase in absolute pressure.

[0027] Referring now to the drawings and initially to FIGURES 1-5C, and specifically to FIGURES 1 and 3, a system 100 for treating a tissue site 102 on a patient 104 with reduced pressure is presented. The system 100 includes a reduced-pressure dressing 106 for disposing proximate the tissue site 102. The system 100 also includes a reduced-pressure treatment unit 108 fluidly connected to the reduced-pressure dressing 106 through a reduced-pressure delivery conduit 110 for applying reduced pressure to the tissue site 102. The reduced-pressure dressing 106 may further include a distribution manifold 112, a sealing member 114, and a reduced-pressure interface 116. The reduced-pressure interface 116 includes a cutting element 118 adapted to form an aperture 120 (see Fig. 5B) in the sealing member 114. Including the cutting element 118 on the reduced-pressure interface 116 provides a number of potential benefits. The benefits may include ease of application and the reduction of error when forming the aperture 120. In a non-limiting example, errors in (1) positioning the aperture 120 on the dressing, (2) sizing of the aperture 120, and (3) the formation of the aperture 120 may be reduced. Incorrectly forming the aperture 120 may leave portions of the

sealing member 114 in a position that can block the aperture 120 when reduced pressure is applied.

[0028] The system 100 may be used with various different types of tissue sites 102. The tissue site 102 may be a wound 122 or wound cavity. As shown in at least FIGURES 5A-5C, the tissue site 102 or wound 122, may be through an epidermis 124 and into a subcutaneous tissue or any other tissue. The tissue site 102 may be the bodily tissue of any human, animal, or other organism, including bone tissue, adipose tissue, muscle tissue, dermal tissue, vascular tissue, connective tissue, cartilage, tendons, ligaments, body cavity or any other tissue. Treatment of the tissue site 102 may include removal of fluids, e.g., exudate or ascites.

[0029] Referring still to FIGURES 1-5C, the distribution manifold 112 is proximate the tissue site 102 and has a first side 128 and a second, tissue-facing side 130. The term “distribution manifold” as used herein generally refers to a substance or structure that is provided to assist in applying reduced pressure to, delivering fluids to, or removing fluids from the tissue site 102. The distribution manifold 112 typically includes a plurality of flow channels or pathways that distribute fluids provided to and removed from the tissue site 102 around the distribution manifold 112. In one illustrative embodiment, the flow channels or pathways are interconnected to improve distribution of fluids provided or removed from the tissue site 102. The distribution manifold 112 may be a biocompatible material that is capable of being placed in contact with the tissue site 102 and distributing reduced pressure to the tissue site 102. Examples of the distribution manifold 112 may include, without limitation, devices that have structural elements arranged to form flow channels, such as, for example, cellular foam, open-cell foam, porous tissue collections, liquids, gels, and foams that include, or cure to include, flow channels. The distribution manifold 112 may be porous and may be made from foam, gauze, felted mat, or any other material suited to a particular biological application. In one embodiment, the distribution manifold 112 is a porous foam and includes a plurality of interconnected cells or pores that act as flow channels. The porous foam may be a polyurethane, open-cell, reticulated foam such as GranuFoam® material manufactured by Kinetic Concepts, Incorporated of San Antonio, Texas. In some situations, the distribution manifold 112 may also be used to distribute fluids such as medications, antibacterials, growth factors, and various solutions to the tissue site 102. Other layers may be included in or on the distribution manifold 112, such as absorptive materials, wicking materials, hydrophobic materials, and hydrophilic materials.

[0030] In one illustrative the distribution manifold 112 may be constructed from bioresorbable materials that do not have to be removed from a patient's body following use of the system 100. Suitable bioresorbable materials may include, without limitation, a polymeric blend of polylactic acid (PLA) and polyglycolic acid (PGA). The polymeric blend may also 5 include without limitation polycarbonates, polyfumarates, and capralactones. The distribution manifold 112 may further serve as a scaffold for new cell-growth, or a scaffold material may be used in conjunction with the distribution manifold 112 to promote cell-growth. A scaffold is a substance or structure used to enhance or promote the growth of cells or formation of tissue, such as a three-dimensional porous structure that provides a template for cell growth. 10 Illustrative examples of scaffold materials include calcium phosphate, collagen, PLA/PGA, coral hydroxy apatites, carbonates, or processed allograft materials.

[0031] The distribution manifold 112 may be covered by the sealing member 114, which may also be referred to as a drape. The sealing member 114 forms a sealed space 132 over the tissue site 102. The sealing member 114 has a first side 134, and a second, tissue-facing side 136. The sealing member 114 may be any material that provides a fluid seal. 15 "Fluid seal," or "seal," means a seal adequate to maintain reduced pressure at a desired site given the particular reduced-pressure source or subsystem involved. The sealing member 114 may, for example, be an impermeable or semi-permeable, elastomeric material. "Elastomeric" means having the properties of an elastomer. Elastomer generally refers to a polymeric 20 material that has rubber-like properties. More specifically, most elastomers have ultimate elongations greater than 100% and a significant amount of resilience. The resilience of a material refers to the material's ability to recover from an elastic deformation. Elastomers that are relatively less resilient may also be used as these elastomers are more likely to tear when faced with the cutting element 118. Examples of elastomers may include, but are not limited 25 to, natural rubbers, polyisoprene, styrene butadiene rubber, chloroprene rubber, polybutadiene, nitrile rubber, butyl rubber, ethylene propylene rubber, ethylene propylene diene monomer, chlorosulfonated polyethylene, polysulfide rubber, polyurethane (PU), EVA film, co-polyester, and silicones. Additional, specific examples of dressing sealing member materials 30 include a silicone drape, 3M Tegaderm® drape, polyurethane (PU) drape such as one available from Avery Dennison Corporation of Pasadena, California. An additional, specific non-limiting example of a dressing sealing member material includes a 30 μ m matt polyurethane film such as the Inspire™ 2317 manufactured by Exopack™ Advanced Coatings of Matthews, North Carolina.

[0032] An attachment device 138 may be used to hold the sealing member 114 against a portion of the patient's intact epidermis 124 or another layer, such as a gasket or additional sealing member. The attachment device 138 may take numerous forms. For example, the attachment device 138 may be a medically acceptable adhesive, such as a pressure-sensitive adhesive, that extends about a periphery or all of the sealing member 114. The attachment device 138 may also be a sealing ring or other device. The attachment device 138 is disposed on the second, tissue-facing side 136 of the sealing member 114. Before use, the attachment device 138 may be covered by a release liner (not shown).

[0033] The reduced-pressure interface 116 may be positioned adjacent to or coupled to the sealing member 114 to provide fluid access to the distribution manifold 112. Another attachment device 152 similar to the attachment device 138 may be used to hold the reduced-pressure interface 116 against the sealing member 114. The reduced-pressure delivery conduit 110 fluidly couples the reduced-pressure treatment unit 108 and the reduced-pressure interface 116. The reduced-pressure interface 116 allows the reduced pressure to be delivered to the tissue site 102. While the amount and nature of reduced pressure applied to a tissue site will typically vary according to the application, the reduced pressure will typically be between -5 mm Hg (-667 Pa) and -500 mm Hg (-66.7 kPa) and more typically between -75 mm Hg (-9.9 kPa) and -300 mm Hg (-39.9 kPa). For example, and not by way of limitation, the pressure may be -12, -12.5, -13, -14, -14.5, -15, -15.5, -16, -16.5, -17, -17.5, -18, -18.5, -19, -19.5, -20, -20.5, -21, -21.5, -22, -22.5, -23, -23.5, -24, -24.5, -25, -25.5, -26, -26.5 kPa or another pressure.

[0034] As shown, the reduced-pressure delivery conduit 110 is a multi-lumen conduit. It should be understood, however, that the reduced-pressure delivery conduit 110 may be in many forms and may comprise a single lumen. The reduced-pressure delivery conduit 110 may include a primary lumen 142 and at least one sensing lumen 144. In one illustrative the primary lumen 142 is a central lumen 146 and the at least one sensing lumen 144 is one or more peripheral lumens 148. The primary lumen 142 and the at least one sensing lumen 144 are adapted to maintain fluid isolation between the primary lumen 142 and the at least one sensing lumen 144 as the reduced-pressure delivery conduit 110 transports fluids from the reduced-pressure interface 116 to the reduced-pressure treatment unit 108. Liquids or exudates communicated from the distribution manifold 112 through the primary lumen 142 are removed from the reduced-pressure delivery conduit 110 and retained within a liquid-collection chamber (not explicitly shown) in fluid communication with the reduced-pressure

treatment unit 108. The at least one sensing lumen 144 fluidly communicates reduced pressure representative of the tissue site 102 to an instrumentation unit 150.

[0035] The reduced-pressure treatment unit 108 may include a liquid-collection chamber, or a collection canister, and the instrumentation unit 150 in fluid communication with a reduced-pressure source 140. The instrumentation unit 150 may include a microprocessor 154 adapted to process pressure signals received by the reduced-pressure delivery conduit 110, monitor the pressure signals, and issue alerts according to a pre-determined pressure configuration. The pre-determined pressure configuration may include a pressure set-up pattern of sustained decrease, increase, and relative stability within an application time period as will be described in more detail with respect to FIGURE 10 below.

[0036] In an illustrative embodiment, the reduced-pressure source 140 is an electrically-driven vacuum pump. In another implementation, the reduced-pressure source 140 may instead be a manually-actuated or manually-charged pump that does not require electrical power. The reduced-pressure source 140 instead may be any other type of reduced pressure pump, or alternatively a wall suction port such as those available in hospitals and other medical facilities. The reduced-pressure source 140 may be housed within or used in conjunction with the reduced-pressure treatment unit 108, which may also include the instrumentation unit 150. The instrumentation unit 150 may include sensors, processing units, alarm indicators, memory, databases, software, display units, and user interfaces that further facilitate the application of reduced pressure treatment to the tissue site 102.

[0037] In one example, pressure-detection sensors (not shown) located in the instrumentation unit 150 may be disposed at or near the reduced-pressure source 140. The pressure-detection sensors may receive pressure data, or a pressure signal, from the reduced-pressure interface 116 via the at least one sensing lumen 144 that is dedicated to delivering reduced pressure data to the pressure-detection sensors. The pressure signal or data may be representative of a pressure at a distal end 156 of the at least one sensing lumen 144. The pressure-detection sensors may communicate with a processing unit that monitors and controls the reduced pressure that is delivered by the reduced-pressure source 140. In one embodiment, the pressure-detection sensors communicate with the processing unit to monitor whether the pressure signal follows the pressure set-up pattern. In the event the pressure signal does not follow the pressure set-up pattern within an application time period that may be predetermined, the instrumentation unit 150 provides an indication to a caregiver. The indication may be in the form of a visual or audible alert or alarm. Other indications may be used. In an alternative, but not mutually exclusive, embodiment, the pressure-detection

sensors may communicate with the processing unit to monitor whether the pressure signal does follow the pressure set-up pattern within an application time period. In the event the pressure signal does follow the pressure set-up pattern, the instrumentation unit 150 provides an indication to the caregiver. The indication that the pressure set-up pattern has been 5 followed may be different than the indication that the pressure set-up pattern has not been followed.

[0038] Referring now primarily to FIGURES 3-5C, an illustrative embodiment of the reduced-pressure interface 116 is presented in more detail. The reduced-pressure interface 116 includes a housing 158, a conduit port 168 coupled to the housing 158, and the attachment 10 device 152 for coupling the reduced-pressure interface 116 to the sealing member 114. The reduced-pressure interface 116 further includes the cutting element 118.

[0039] The housing 158 may have a flange portion 160 and a cavity wall portion 162. The cavity wall portion 162 forms a cavity 164 having a tissue-facing cavity opening 166. The conduit port 168 is coupled to or formed as part of the cavity wall portion 162 of the 15 housing 158. The conduit port 168 includes a conduit aperture 170 whereby the conduit port 168 is adapted to receive the reduced-pressure delivery conduit 110. The attachment device 152 may be coupled to a tissue-facing side 172 of the flange portion 160 for coupling the housing 158 to the first side 134 of the sealing member 114. The housing 158 is made of a semi-rigid material that is capable of collapsing under a force such as a driving force 174. In a 20 non-limiting example, the reduced-pressure interface 116, and thus the housing 158, may be made from a plasticized polyvinyl chloride (PVC), polyurethane, cyclic olefin copolymer elastomer, thermoplastic elastomer, poly acrylic, silicone polymer, and polyether block amide copolymer.

[0040] The cutting element 118 may be at least temporarily coupled to the housing 158 25 proximate to the tissue-facing cavity opening 166. The cutting element 118 is adapted to form the aperture 120 in the sealing member 114 when the cutting element 118 is driven into the sealing member 114 with the driving force 174. The driving force 174 may also cause the cutting element 118 to penetrate or cut a portion of the distribution manifold 112. The driving 30 force 174 may be manually applied to an exterior 184 of the reduced-pressure interface 116 causing the housing 158 to collapse and thereby driving or pushing the cutting element 118 into the sealing member 114. In another embodiment, the driving force 174 is applied by applying reduced pressure to the cavity 164 such that a cavity pressure (P_c) in the cavity 164 is less than a threshold pressure (P_t). When the cavity pressure (P_c) is less than the threshold pressure (P_t), the cavity wall portion 162 collapses and with continued reduced pressure

impacts the cutting element 118 thereby driving a portion of the cutting element 118 through the sealing member 114. The threshold pressure (P_t) is at least in part dependent on the type and thickness of the material used for the housing 158. In the event reduced pressure is applied to the cavity 164, a tensile force may be applied to the sealing member 114 causing the 5 sealing member 114 to pull into the cavity 164. This movement further assists with the cutting element 118 moving into the sealing member 114.

[0041] In one embodiment, the cutting element 118 includes a base member 176 and a stylus member 178 coupled to the base member 176. The stylus member 178 has a leading edge 180 and is configured to perforate the sealing member 114 to form the aperture 120 in the 10 sealing member 114. In one embodiment, the leading edge 180 is serrated. In another embodiment, the leading edge 180 is serrated or configured to perforate the sealing member 114 orthogonally. The sealing member 114 may be perforated orthogonally to inhibit the cut sealing member 114 from blocking the reduced-pressure delivery conduit 110 during reduced pressure therapy. The base member 176 may be sized and configured to form an interference 15 fit with the tissue-facing cavity opening 166, whereby the cutting element 118 is releasably coupled to the housing 158. Thus, in one embodiment, the cutting element 118 may be removed prior to use if not desired or after perforating the sealing member 114.

[0042] The cutting element 118 may have a piercing length (L_p) extending the length (L) of the stylus member 178. The length (L) of the stylus member 178 extends from the base 20 member 176 to a tip 182 of the stylus member 178. In one embodiment, the piercing length (L_p) is less than 3 centimeters. In another embodiment, the piercing length (L_p) is less than 2 centimeters. The distribution manifold 112 may have a thickness greater than T when subject to reduced pressure such that the piercing length (L_p) of the cutting element 118 is less than the thickness T, i.e., $L_p < T$. One benefit of the piercing length (L_p) being less than the 25 thickness, T, of the distribution manifold 112 under reduced pressure is that the cutting element 118 cannot completely cut through the distribution manifold 112 and reach the tissue site 102.

[0043] As previously mentioned, the cutting element 118 may be only temporarily coupled to the housing 158. In one embodiment, the cutting element 118 may be removed by 30 a care giver. In another embodiment, the cutting element 118 may be formed from a liquid soluble material such as a water soluble material adapted to allow the cutting element 118 to dissolve. For example, the water soluble material may include at least one of the following: Polyvinyl alcohol (PVOH), polyvinyl pyrrolidone, hydroxyl and carboxyl modified cellulose, hydroxyl and carboxyl modified acrylics, starch, sugars (sucrose, glucose, fructose), weak

acids (tartaric, citric, malic), salts (sodium chloride, sodium carbonate, sodium bicarbonate), polyethylene oxide (PEO), polyethylene glycol (PEG). The cutting element 118 may dissolve as liquids are removed from the tissue site 102. Reduced pressure is applied to the reduced-pressure interface 116 after perforating the sealing member 114 typically causing liquids to be 5 removed from the tissue site 102. After a sufficient amount of time, liquids removed from the tissue site 102 cause the cutting element 118 to substantially dissolve. The cutting element 118 may dissolve within 2 minutes, 5 minutes, 10 minutes, or another time period. As the cutting element 118 is dissolved it is removed by the reduced-pressure delivery conduit 110 with liquids from the tissue site 102. A liquid, e.g., saline solution, may also be introduced 10 through the reduced-pressure delivery conduit 110 or otherwise to dissolve the cutting element 118.

[0044] As shown in FIGURE 5C, once the cutting element 118 has substantially dissolved, reduced pressure applied through the reduced-pressure interface 116 creates sufficient reduced pressure in the cavity 164 to pull a portion of the distribution manifold 112 15 into the cavity 164 such that the distribution manifold 112 abuts a distal end 186 of the reduced-pressure delivery conduit 110 to include a distal aperture 188 of the at least one sensing lumen 144. Allowing the distribution manifold 112 to completely abut the distal end 186 of the reduced-pressure delivery conduit 110 may help ensure fluid isolation between each 20 of the lumens in the reduced-pressure delivery conduit 110. The distribution manifold 112 may provide a barrier between the primary lumen 142 and the at least one sensing lumen 144. Additionally, having the reduced-pressure delivery conduit 110 in direct contact with the distribution manifold 112 may help ensure that there is a constant low velocity liquid flow into 25 the reduced-pressure delivery conduit 110 which may minimize the instance of aerosolized particles being deposited around the at least one sensing lumen 144 and may also provide a filter to liquids entering the at least one sensing lumen 144.

[0045] In operation, a caregiver may treat the tissue site 102 on the patient 104 with a method that includes disposing the distribution manifold 112 proximate to the tissue site 102. The distribution manifold 112 and a portion of intact epidermis 124 of the patient 104 is covered with the sealing member 114 to form the sealed space 132 in which the distribution 30 manifold 112 is disposed. The reduced-pressure interface 116 is coupled to the sealing member 114. The reduced-pressure delivery conduit 110 is fluidly coupled on one end to the reduced-pressure source 140 and on the opposing end to the reduced-pressure interface 116. The driving force 174 is then applied to the reduced-pressure interface 116 with sufficient

strength to cause the cutting element 118 to perforate (e.g., pierce, tear, cut or otherwise create the aperture 120) the sealing member 114.

[0046] In one embodiment, the reduced-pressure interface 116 includes the housing 158 having the wall portion, wherein the wall portion forms the cavity 164 having the tissue-facing cavity opening 166. The housing 158 is formed of a semi-rigid material that collapses when under reduced pressure less than the threshold pressure (P_t). The conduit port 168 is coupled to the wall portion of the housing 158. The conduit port 168 is further coupled to the reduced-pressure delivery conduit 110. Reduced pressure is supplied to the reduced-pressure interface 116 through the reduced-pressure delivery conduit 110 and the conduit port 168.

10 When reduced pressure levels in the cavity 164 are less than the threshold pressure (P_t), the wall portion collapses under the driving force 174 and impacts the cutting element 118, driving a portion of the cutting element 118 through the sealing member 114 to perforate the sealing member 114..

[0047] In one embodiment, in response to the sealing member 114 being perforated, liquid is removed from the tissue site 102 through the reduced-pressure delivery conduit 110. Liquid is removed from the tissue site 102 by virtue of reduced pressure. The liquid causes the cutting element 118 to dissolve. Once the cutting element 118 has substantially dissolved, reduced pressure within the cavity 164 of the reduced-pressure interface 116 causes a portion of the distribution manifold 112 to be pulled into the cavity 164 and abut the reduced-pressure delivery conduit 110. Fluid may then be directly transferred from the distribution manifold 112 to the reduced-pressure delivery conduit 110 without going through an additional medium or open space.

[0048] Referring now primarily to FIGURES 6-9C, another illustrative embodiment of a reduced-pressure interface 216 is presented. The reduced-pressure interface 216 is analogous in many respects to the reduced-pressure interface 116 of FIGURES 3-5C. The reduced-pressure interface 216 includes a housing 258 and a cutting element 218. The housing 258 may have a flange portion 260 and a cavity wall portion 262. The flange portion 260 may be coupled to the sealing member 114 by the attachment device 152. The cavity wall portion 262 is collapsible under reduced pressure. The cavity wall portion 262 may include a bellows configuration 290 for permitting the cavity wall portion 262 to collapse when a cavity 164 pressure (P_c) inside a cavity 264 is less than a threshold pressure (P_t) on an absolute pressure side.

[0049] The cutting element 218 may include a conduit adapter 292, an adapter flange 294, a tube extension 296, a base member 276, and a stylus member 278. The conduit adapter

292 is configured to receive the reduced-pressure delivery conduit 110 to provide fluid communication between the reduced-pressure treatment unit 108 and the tissue site 102. The conduit adapter 292 includes a protrusion 293 for engaging the primary lumen 142 of the reduced-pressure delivery conduit 110. The protrusion 293 may be sized and configured to extend into the primary lumen 142 and to form an interference fit. The protrusion 293 may help maintain fluid isolation between the primary lumen 142 and the at least one sensing lumen 144. The adapter flange 294 is positioned on an exterior 284 of the cavity wall portion 262. The tube extension 296 is connected to the adapter flange 294 and is sized and configured to mate with a conduit aperture 270. The tube extension 296 is further configured to extend through the conduit aperture 270. In a specific, non-limiting example, the conduit adapter, 292, the adapter flange 294, and the tube extension 296 may be formed from materials to include plasticized polyvinyl chloride (PVC), polyurethane, cyclic olefin copolymer elastomer, thermoplastic elastomer, poly acrylic, silicone polymer, and polyether block amide copolymer.

15 **[0050]** The base member 276 may be at least temporarily coupled to the tube extension 296. The stylus member 278 is directly coupled to the base member 276 and may include a first blade 297 and a second blade 299 configured to make orthogonal cuts in the sealing member 114 when the housing 258 is compressed with a driving force 274 thereby impacting the cutting element 218. The stylus member 278 is thus driven into the sealing member 114.

20 The driving force 274 may be manually applied to the exterior 284 of the reduced-pressure interface 216 causing the housing 258 to collapse and thereby driving or pushing the cutting element 218 into the sealing member 114. In another embodiment, the driving force 274 is applied by applying reduced pressure to the cavity 264 such that the cavity pressure (P_c) in the cavity 264 is less than a threshold pressure (P_t). When the cavity pressure (P_c) in the cavity 264 is less than the threshold pressure (P_t), the cavity wall portion 262 collapses and impacts the cutting element 218. With continued reduced pressure, a portion of the cutting element 218 is driven through the sealing member 114. The threshold pressure (P_t) is at least in part dependent on the type and thickness of material used for the housing 258. In the event reduced pressure is applied to the cavity 264, a tensile force 273 may be applied to the sealing member 114 causing the sealing member 114 to be pulled into the cavity 264. This movement helps the cutting element 218 to be driven into the sealing member 114.

30 **[0051]** As previously mentioned, the base member 276 may be only temporarily coupled to the housing 258. In one embodiment, the base member 276 and the stylus member 278 may be formed from a liquid soluble material such as a water soluble material adapted to

allow the cutting element 118 to dissolve. The water soluble material may include at least one of the following: Polyvinyl alcohol (PVOH), polyvinyl pyrrolidone, hydroxyl and carboxyl modified cellulose, hydroxyl and carboxyl modified acrylics, starch, sugars (sucrose, glucose, fructose), weak acids (tartaric, citric, malic), salts (sodium chloride, sodium carbonate, sodium bicarbonate), polyethylene oxide (PEO), polyethylene glycol (PEG). The base member 276 and the stylus member 278 may dissolve as liquids are removed from the tissue site 102.

Reduced pressure is applied to the reduced-pressure interface 216 typically causing liquids to be removed from the tissue site 102. After a sufficient amount of time, liquids removed from the tissue site 102 may cause the base member 276 and the stylus member 278 to substantially dissolve. The base member 276 and the stylus member 278 may dissolve within 2 minutes, 5 minutes, 8 minutes, 10 minutes, or another time period. As the base member 276 and the stylus member 278 are dissolved, the base member 276 and the stylus member 278 are removed by the reduced-pressure delivery conduit 110 with the liquids from the tissue site 102. While the base member 276 and the stylus member 278 may be dissolvable, it is worth noting that the conduit adapter 292, the adapter flange 294, and the tube extension 296 do not dissolve.

[0052] Once the base member 276 and the stylus member 278 have substantially dissolved, reduced pressure applied through the reduced-pressure interface 216 may sufficient reduced pressure in the cavity 264 to pull a portion of the distribution manifold 112 into the cavity 264 and the primary lumen 142 of the reduced-pressure delivery conduit 110. The distribution manifold 112 abuts the distal end 186 of the reduced-pressure delivery conduit 110 including the distal aperture 188 of the at least one sensing lumen 144. Allowing the distribution manifold 112 to completely abut the distal end 186 of the reduced-pressure delivery conduit 110 may help ensure fluid isolation between each of the lumens in the reduced-pressure delivery conduit 110.

[0053] Referring now primarily to FIGURE 10, a schematic diagram of a pressure set-up pattern is presented. The pressure set-up pattern may be a pre-determined pressure configuration. Pressure-detection sensors may communicate with a processing unit to monitor whether pressure signals received from a reduced-pressure interface follow or is consistent with the pressure set-up pattern. The pressure set-up pattern may be representative of whether a cutting element of the reduced-pressure interface has pierced a sealing member. The pressure set-up pattern may represent four main events. First, a period of sustained pressure decrease (reduced pressure increase) may be indicative of a period of time prior to the cutting element piercing the sealing member. This segment is shown generally by reference numeral

302. During this period of time, pressure is decreasing in a cavity of the reduced-pressure interface causing the cavity to collapse. Second, a threshold pressure (P_t) is reached and pressure increases (reduced pressure decreases) indicating that the cutting element has pierced the sealing member. This segment is generally shown by numeral 304. The pressure should
5 increase as the pressure in the sealed space beneath the sealing member stabilizes. And third, a period of pressure stability is reached as shown generally as reference numeral 306.

10 [0054] Although the present invention and its advantages have been disclosed in the context of certain illustrative, non-limiting embodiments, it should be understood that various changes, substitutions, permutations, and alterations can be made without departing from the scope of the invention as defined by the appended claims. It will be appreciated that any
15 feature that is described in connection to any one embodiment may also be applicable to any other embodiment.

15 [0055] It will be understood that the benefits and advantages described above may relate to one embodiment or may relate to several embodiments. It will further be understood that reference to 'an' item refers to one or more of those items.

[0056] The steps of the methods described herein may be carried out in any suitable order, or simultaneously where appropriate.

[0057] Where appropriate, aspects of any of the examples described above may be combined with aspects of any of the other examples described to form further examples
20 having comparable or different properties and addressing the same or different problems.

[0058] It will be understood that the above description of preferred embodiments is given by way of example only and that various modifications may be made by those skilled in the art. The above specification, examples and data provide a complete description of the structure and use of exemplary embodiments of the invention. Although various embodiments
25 of the invention have been described above with a certain degree of particularity, or with reference to one or more individual embodiments, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of the claims.

CLAIMS

We claim:

1. A reduced-pressure interface for providing reduced pressure through a sealing member to a distribution manifold, the reduced-pressure interface comprising:

5 a housing having a flange portion and a cavity wall portion;
wherein the cavity wall portion forms a cavity having a tissue-facing cavity opening;
a conduit port coupled to the cavity wall and having a conduit aperture, wherein the conduit port is adapted to receive a reduced-pressure delivery conduit;
10 an attachment device coupled to a tissue-facing side of the flange portion of the housing, the attachment device for coupling the housing to the sealing member; and
a cutting element coupled to the housing proximate to the tissue-facing cavity opening, the cutting element configured to form an aperture in the sealing member when the cutting element is driven into the sealing member with a
15 driving force.

2. The reduced-pressure interface of claim 1, wherein the cutting element comprises:

20 a base member;
a stylus member coupled to the base member, wherein the stylus member has a leading edge and is configured to perforate the sealing member to form an access aperture in the sealing member and to apply a tensile force on the access aperture.

3. The reduced-pressure interface of claim 2, wherein a piercing length (L_p) of the cutting element is less than 3 centimeters.

25 4. The reduced-pressure interface of claim 2, wherein a piercing length (L_p) of the cutting element is less than 2 centimeters.

5. The reduced-pressure interface of claim 2, wherein the base member is sized and configured to form an interference fit with the tissue-facing cavity opening, whereby the cutting element is releasably coupled to the housing.

6. The reduced-pressure interface of claim 2 or any of the preceding claims, wherein the stylus member has a first blade and a second blade configured to make orthogonal cuts in the sealing member.
7. The reduced-pressure interface of claim 1 or any of the preceding claims, wherein the attachment device is an adhesive.
8. The reduced-pressure interface of claim 1 or any of the preceding claims, wherein the cutting element is formed from a water soluble material.
9. The reduced-pressure interface of claim 8, wherein the water soluble material comprises at least one of the following: Polyvinyl alcohol (PVOH), polyvinyl pyrrolidone, hydroxyl and carboxyl modified cellulose, hydroxyl and carboxyl modified acrylics, starch, sugars (sucrose, glucose, fructose), weak acids (tartaric, citric, malic), salts (sodium chloride, sodium carbonate, sodium bicarbonate), polyethylene oxide (PEO), polyethylene glycol (PEG).
10. The reduced-pressure interface of claim 1 or any of the preceding claims, wherein the housing is made a semi-rigid material that collapses when exposed to a pressure (P_c) in the cavity that is less than a threshold pressure (P_t).
11. The reduced-pressure interface of claim 1 or any of claims 3-10, wherein the cutting element further comprises a conduit adapter for receiving a reduced-pressure conduit and having an adapter flange on an exterior of the cavity wall and having a tube extension sized and configured to mate with the conduit aperture, wherein the cutting element further comprises a base member and a stylus member, and wherein the base member is coupled to the tube extension.

12. A system for treating a tissue site on a patient with reduced pressure, the system comprising:

- a distribution manifold for placing proximate to the tissue site;
- a sealing member for covering the distribution manifold and a portion of intact epidermis of the patient to form a sealed space;
- 5 a reduced-pressure interface for providing reduced pressure through the sealing member to the distribution manifold;
- a reduced-pressure source;
- 10 a reduced-pressure delivery conduit for fluidly coupling the reduced-pressure source to the reduced-pressure interface;
- wherein the reduced-pressure interface comprises:
 - a housing having a flange portion and a cavity wall portion;
 - wherein the cavity wall portion forms a cavity having a tissue-facing cavity opening;
 - 15 a conduit port coupled to the cavity wall and having a conduit aperture,
 - wherein the conduit port is adapted to receive the reduced-pressure delivery conduit;
 - an attachment device coupled to a tissue-facing side of the flange portion of the housing, the attachment device for coupling the housing to the sealing member; and
- 20 a cutting element coupled to the housing proximate to the tissue-facing cavity opening, the cutting element adapted to form an aperture in the sealing member when the cutting element is driven into the sealing member with a driving force.

25 13. The system of claim 12, wherein the cutting element comprises:

- a base member;
- a stylus member coupled to the base member, wherein the stylus member has a leading edge and is configured to perforate the sealing member to form an access aperture in the sealing member and to apply a tensile force on the access aperture.

14. The system of claim 12 or claim 13, wherein the distribution manifold has a thickness greater than T when subject to reduced pressure, wherein the cutting element has a piercing length (L_p), and wherein $L_p < T$.
15. The system of claim 13, wherein the base member is sized and configured to form an interference fit with the tissue-facing cavity opening, whereby the cutting element is releasably coupled to the housing.
16. The system of claim 13, wherein the stylus member has a first blade and a second blade configured to make orthogonal cuts in the sealing member.
17. The system of claim 12 or any of claims 13-16, wherein the cutting element is formed from a water soluble material.
18. The system of claim 17, wherein the water soluble material comprises at least one of the following: Polyvinyl alcohol (PVOH), polyvinyl pyrrolidone, hydroxyl and carboxyl modified cellulose, hydroxyl and carboxyl modified acrylics, starch, sugars (sucrose, glucose, fructose), weak acids (tartaric, citric, malic), salts (sodium chloride, sodium carbonate, sodium bicarbonate), polyethylene oxide (PEO), polyethylene glycol (PEG).
19. The system of claim 12 or any of claims 13-18, wherein the housing is made a semi-rigid material that collapses when exposed to a pressure (P_c) in the cavity that is less than a threshold pressure (P_t).
20. The system of claim 12 or any of claims 14-19, wherein the cutting element further comprises a conduit adapter for receiving a reduced-pressure conduit and having an adapter flange on an exterior of the cavity wall and having a tube extension sized and configured to mate with the conduit aperture, wherein the cutting element further comprises a base member and a stylus member, and wherein the base member is coupled to the tube extension.

21. The system of claim 12 or any of claims 13-20, wherein the reduced-pressure delivery conduit comprises a multi-lumen conduit having a primary lumen and at least one sensing lumen, and further comprising a instrumentation unit fluidly coupled to the at least one sensing lumen, wherein the instrumentation unit includes a microprocessor and is adapted to:

5 to:

process a pressure signal representative of a pressure at distal end of the at least one sensing lumen;
monitor the pressure signal;
issue an alert if the pressure signal does not follow a pattern of sustained decrease, increase, and stability within an application time period.

10

22. A method for treating a tissue site on a patient with reduced pressure, the method comprising:

disposing a distribution manifold proximate to the tissue site;
covering the distribution manifold and a portion of intact epidermis of the patient
5 with a sealing member to form a sealed space in which the distribution
manifold is disposed, wherein the sealing member has a first side and a
second, tissue-facing side;
providing a reduced-pressure source;
coupling a reduced-pressure interface proximate to the first side of the sealing
10 member;
fluidly coupling a reduced-pressure delivery conduit between the reduced-pressure
source and the reduced-pressure interface;
wherein the reduced-pressure interface comprises:
a housing having a wall portion,
15 wherein the wall portion forms a cavity having a tissue-facing cavity
opening,
a conduit port coupled to the wall portion for receiving the reduced-pressure
delivery conduit,
an attachment device for coupling the reduced-pressure interface to the
20 sealing member, and
a cutting element coupled to the housing proximate to the tissue-facing
cavity opening, the cutting element configured to perforate the
sealing member when the cutting element is driven into the sealing
member with a driving force; and
25 applying the driving force to the reduced-pressure interface of sufficient strength to
cause the cutting element to perforate the sealing member.

23. The method of claim 22, wherein the step of coupling the reduced-pressure interface proximate to the first side of the sealing member comprises using the attachment device of the reduced-pressure interface to adhere the reduced-pressure interface to the sealing member.
- 5 24. The method of claim 22 or claim 23, wherein the attachment device is an adhesive.
25. The method of claim 22 or any of claims 23-24, wherein the reduced-pressure delivery conduit is a multi-lumen conduit having a primary lumen and at least one sensing lumen.
- 10 26. The method of claim 22 or any of claims 23-25 , wherein the reduced-pressure delivery conduit is a multi-lumen conduit having a primary lumen and at least one sensing lumen, and further comprising applying reduced pressure through the reduced-pressure interface to create sufficient reduced pressure in the cavity to pull a portion of the distribution manifold into the cavity such that the distribution manifold abuts a distal aperture of the at least one sensing lumen.
- 15 27. The method of claim 22 or any of claims 23-26, wherein the step of applying the driving force to the reduced-pressure interface comprises manually applying the driving force an exterior of the reduced-pressure interface.
- 20 28. The method of claim 22 or any of claims 23-26, wherein the housing is formed of a semi-rigid material that collapses when under reduced pressure less than a threshold pressure (P_t), and wherein the step of applying the driving force to the reduced-pressure interface comprises applying reduced pressure to the cavity less than the threshold pressure (P_t) such that the wall portion collapse and impact the cutting element driving a portion of the cutting element through the sealing member.
- 25 29. The method of claim 22 or any of claims 23-28, wherein the cutting element is formed from a liquid soluble material and further comprising providing reduced pressure to the reduced-pressure interface for a sufficient time after perforating the sealing member such that liquids are removed from the tissue site and such that the cutting element substantially dissolves.

30. The method of claim 22 or any of claims 23-29, wherein the cutting element comprises:

a base member;
a stylus member coupled to the base member, wherein the stylus member has a leading edge and is configured to perforate the sealing member to form an access aperture in the sealing member and to apply a tensile force on the access aperture.

5

31. The method of claim 22 or any of claims 23-30, wherein the distribution manifold has a thickness greater than T when subject to reduced pressure, wherein the cutting element has a piercing length (L_p), and wherein $L_p < T$.

10 32. The method of claim 30, wherein the base member is sized and configured to form an interference fit with the tissue-facing cavity opening, whereby the cutting element is releasably coupled to the housing.

33. The method of claim 30, wherein the stylus member has a first blade and a second blade configured to make orthogonal cuts in the sealing member.

15 34. The method of claim 22 or any of claims 23-33, wherein the cutting element is formed from a water soluble material.

35. The method of claim 34, wherein the water soluble material comprises at least one of the following: Polyvinyl alcohol (PVOH), polyvinyl pyrrolidone, hydroxyl and carboxyl modified cellulose, hydroxyl and carboxyl modified acrylics, starch, sugars (sucrose, glucose, fructose), weak acids (tartaric, citric, malic), salts (sodium chloride, sodium carbonate, sodium bicarbonate), polyethylene oxide (PEO), polyethylene glycol (PEG).

20 36. The method of claim 22, wherein the cutting element further comprises a conduit adapter for receiving a reduced-pressure conduit and having an adapter flange on an exterior of the wall portion and having a tube extension sized and configured to mate with a conduit

25 aperture, wherein the cutting element further comprises base member and a stylus member, and wherein the base member is coupled to the tube extension.

37. The method of claim 22 or any of claims 23-24, 27-36, wherein the reduced-pressure delivery conduit comprises a multi-lumen conduit having a primary lumen and at least one sensing lumen, and further comprising:

5 providing an instrumentation unit fluidly coupled to the at least one sensing lumen, wherein the instrumentation unit includes a microprocessor and is adapted to:

process a pressure signal representative of a pressure at distal end of the at least one sensing lumen,

monitor the pressure signal,

10 issue an alert if the pressure signal does not follow a pressure set-up pattern (a pattern of sustained decrease, increase, and stability) within a application time period; and

using the instrument unit to monitor the pressure signal representing the pressure at the distal end of the at least one sensing lumen; and

15 providing an indication if the pressure signal does not follow the pressure set-up pattern.

38. The method of claim 37, wherein the instrumentation is adapted to issue an alert if the pressure signal does not follow the pressure set-up pattern (a pattern of sustained decrease, increase, and stability) within a application time period or providing acceptable indication

20 if the pressure signal follows the pressure set-up pattern within the application time period; and further comprising providing an indication if the pressure signal does not follow the pressure set-up pattern or another indication if the pressure signal does follow the pressure set-up pattern.

39. An interface for providing reduced pressure through a drape to a manifold, the interface comprising:

- 5 a housing having a flange portion and a cavity wall portion, wherein the cavity wall portion forms a cavity, and wherein a cavity wall aperture is formed within the cavity wall portion for receiving a tube;
- 10 a coupler positioned on a tissue-facing side of the flange portion of the housing, the coupler for attaching the housing to the drape; and a protrusion coupled to the housing, the protrusion extending beyond the tissue-facing side of the flange portion of the housing, the protrusion configured to form an aperture in the drape when the protrusion is driven into the drape by the reduced pressure.

40. A system for treating a wound with reduced pressure, the system comprising:

- a manifold for positioning adjacent the wound;
- a drape for covering the manifold and a portion of epidermis of the patient to form a sealed space;

5 a reduced-pressure interface for providing reduced pressure through the drape to the manifold;

- a reduced-pressure source;
- a conduit for fluidly coupling the reduced-pressure source to the reduced-pressure interface;

10 wherein the reduced-pressure interface comprises:

- a housing having a flange portion and a cavity wall portion, wherein the cavity wall portion forms a cavity, and wherein a cavity wall aperture is formed within the cavity wall portion for receiving a tube;

15 a coupler positioned on a tissue-facing side of the flange portion of the housing, the coupler for attaching the housing to the drape; and

- a protrusion coupled to the housing, the protrusion extending beyond the tissue-facing side of the flange portion of the housing, the protrusion configured to form an aperture in the drape when the protrusion is driven into the drape by the reduced pressure.

20

41. A method for treating a wound on a patient with reduced pressure, the method comprising:

disposing a manifold proximate to the wound;

covering the manifold and a portion of epidermis of the patient with a drape to form a sealed space in which the manifold is disposed, wherein the drape has a

5 first side and a second, tissue-facing side;

providing a reduced-pressure source;

coupling a reduced-pressure interface proximate to the first side of the drape;

fluidly coupling a tube between the reduced-pressure source and the reduced-

10 pressure interface;

wherein the reduced-pressure interface comprises:

a housing having a flange portion and a cavity wall portion, wherein the cavity wall portion forms a cavity, and wherein a cavity wall aperture is formed within the cavity wall portion for receiving a tube;

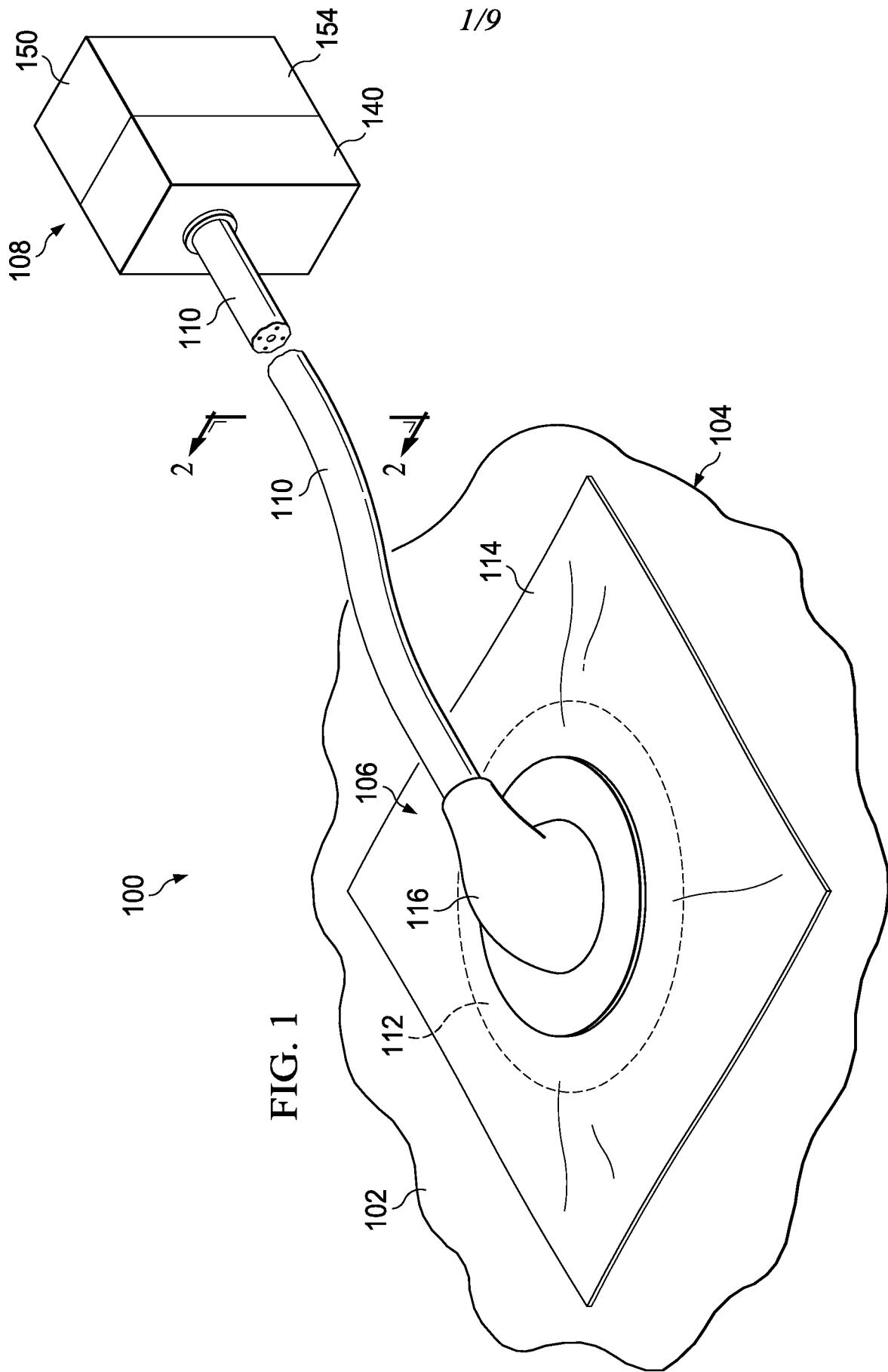
15 a coupler positioned on a tissue-facing side of the flange portion of the housing, the coupler for attaching the housing to the drape; and

a protrusion coupled to the housing, the protrusion extending beyond the tissue-facing side of the flange portion of the housing, the protrusion configured to form an aperture in the drape when the protrusion is

20 driven into the drape with a driving force; and

applying the driving force to the reduced-pressure interface of sufficient strength to cause the protrusion to perforate the drape.

42. The devices, systems, and methods described and disclosed herein.



2/9

FIG. 2

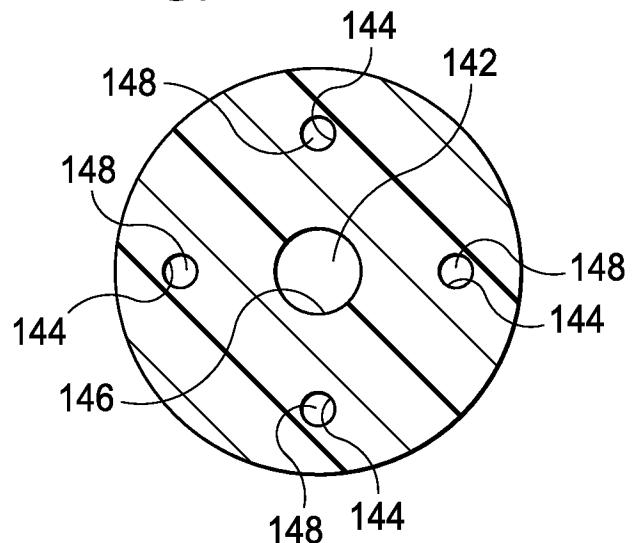


FIG. 3

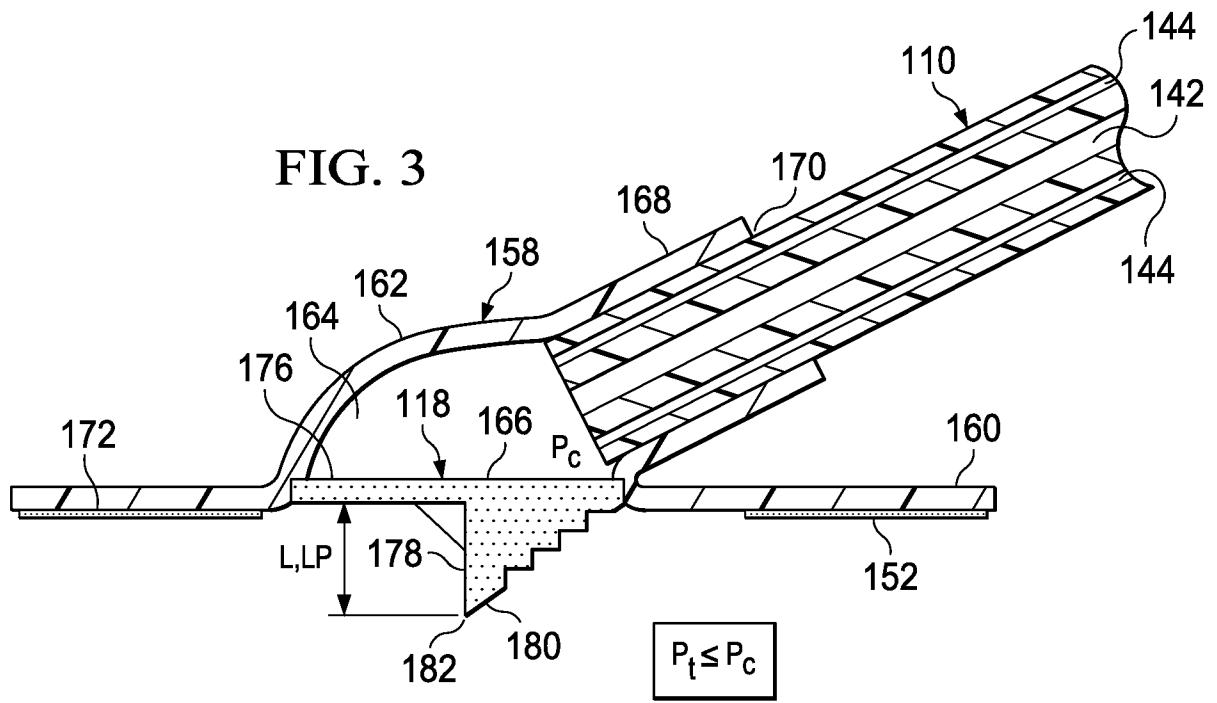
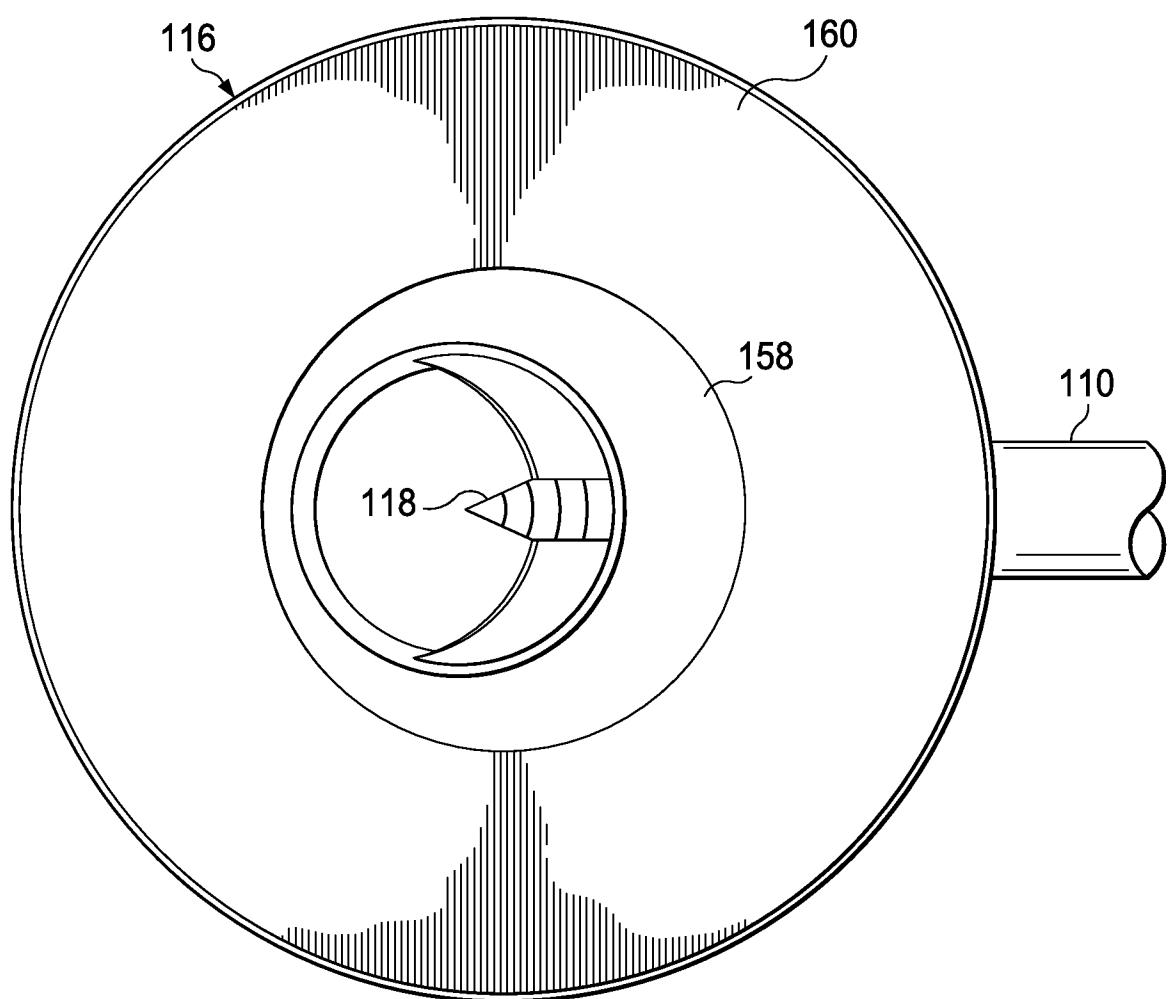


FIG. 4



4/9

FIG. 5A

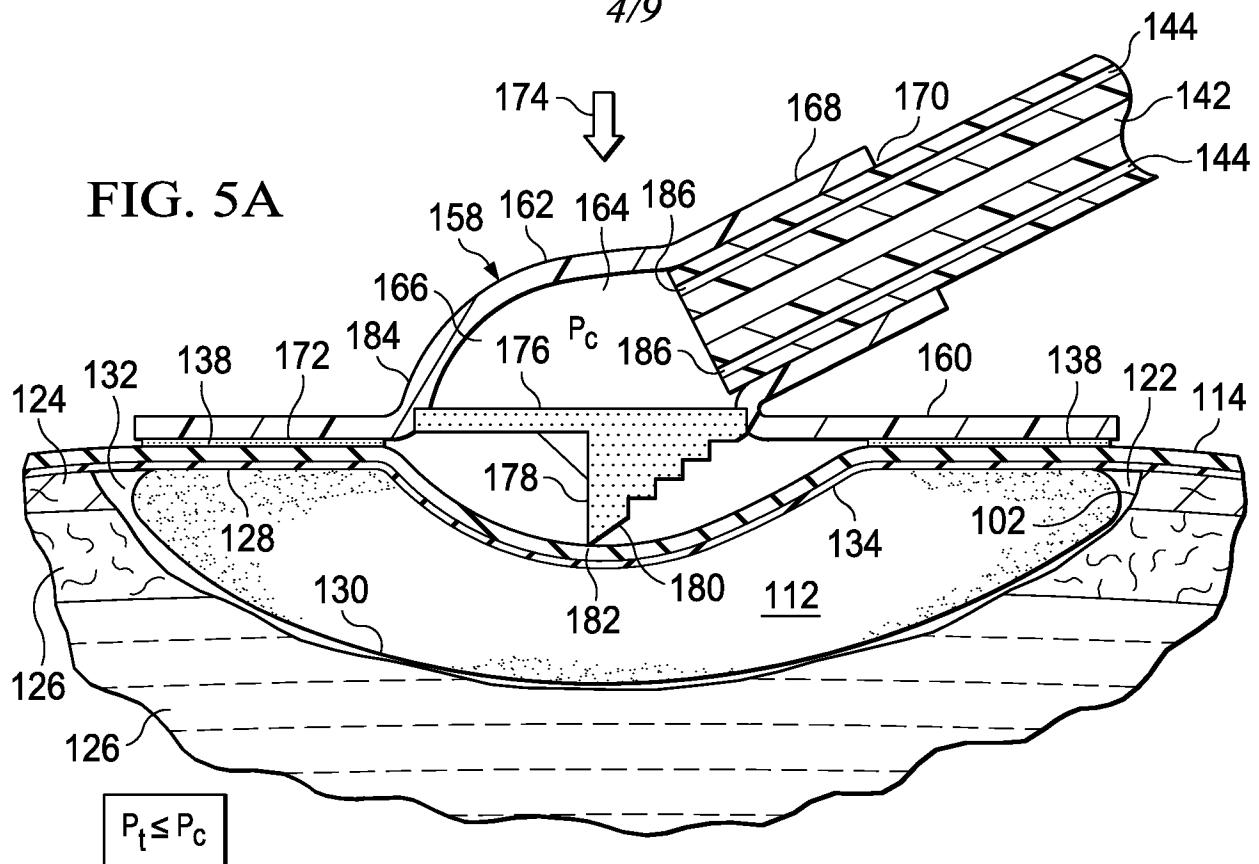
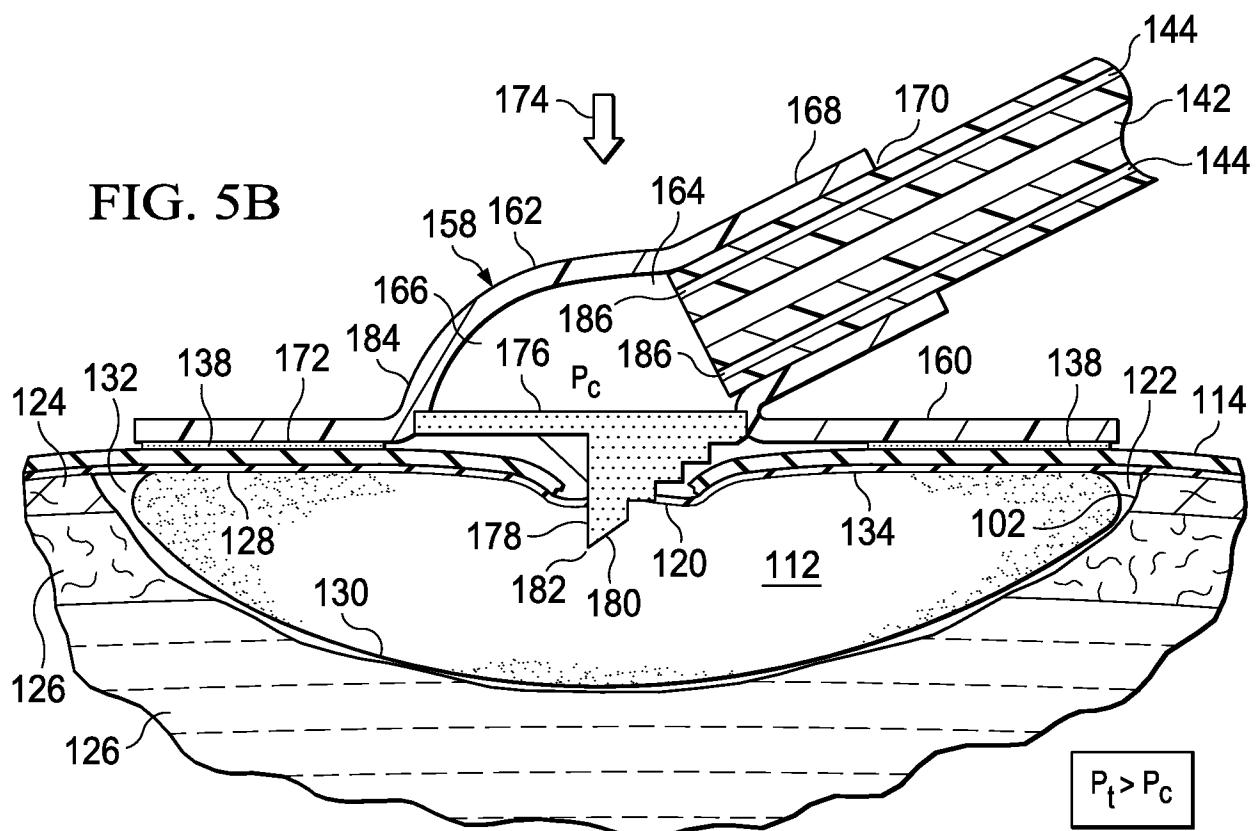


FIG. 5B



5/9

FIG. 5C

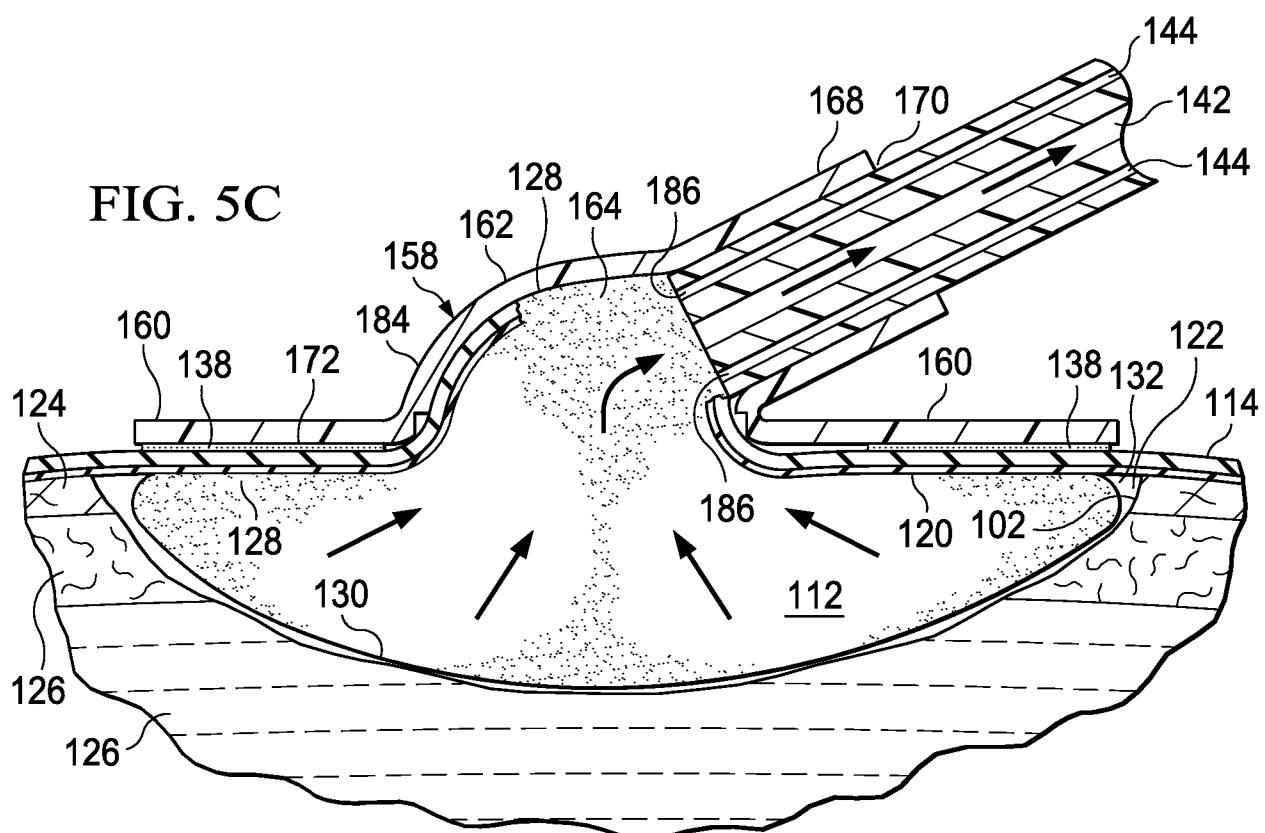
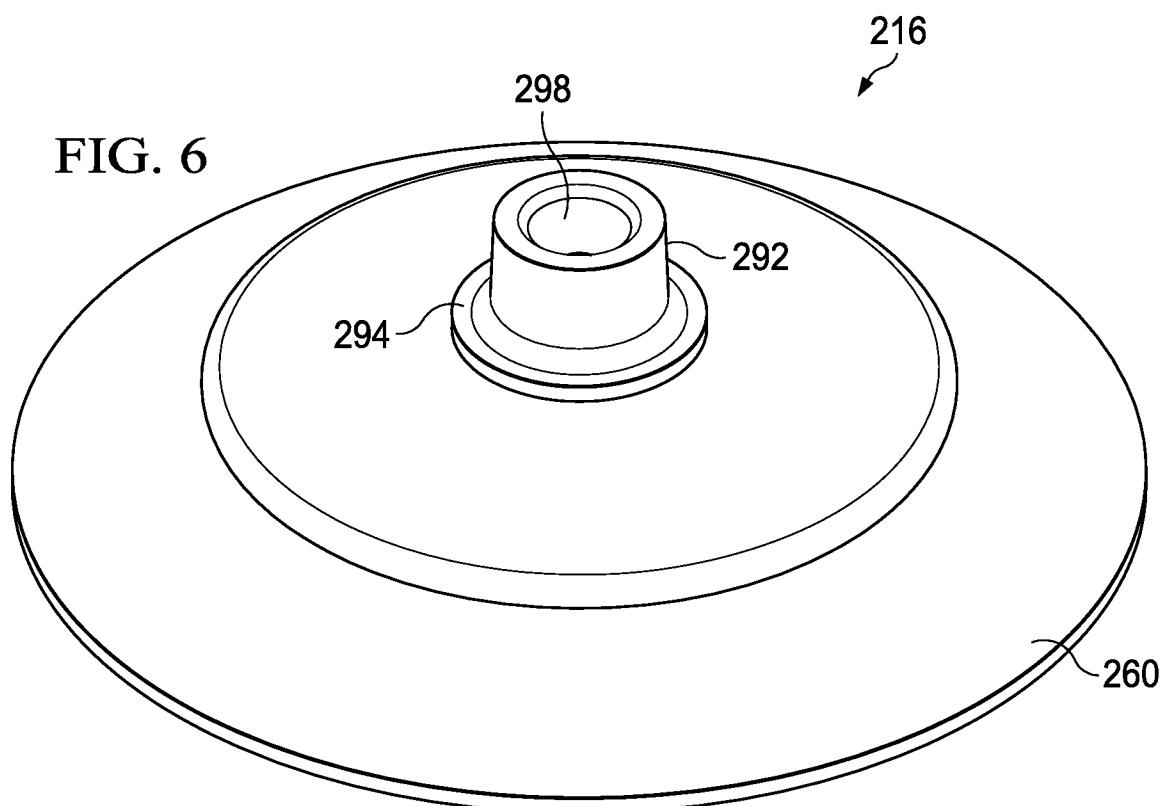


FIG. 6



6/9

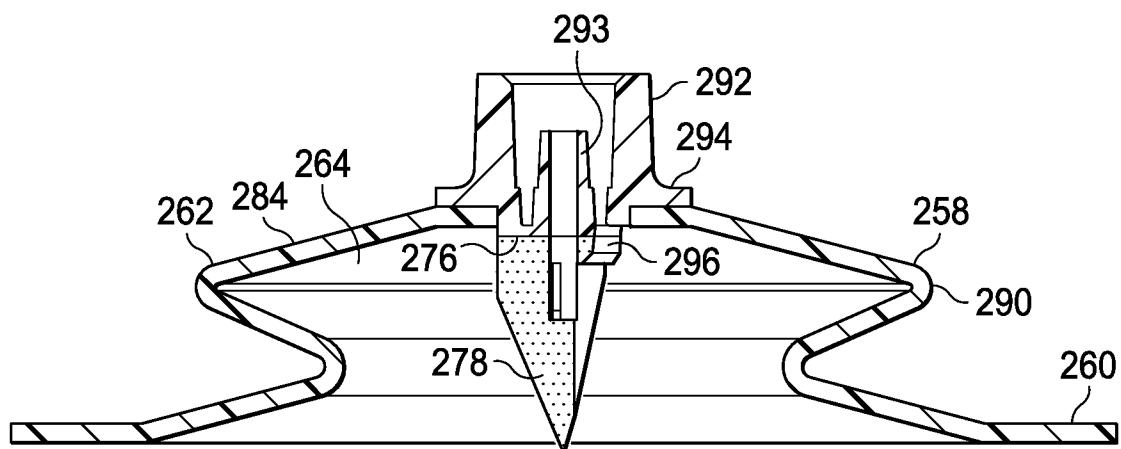


FIG. 7

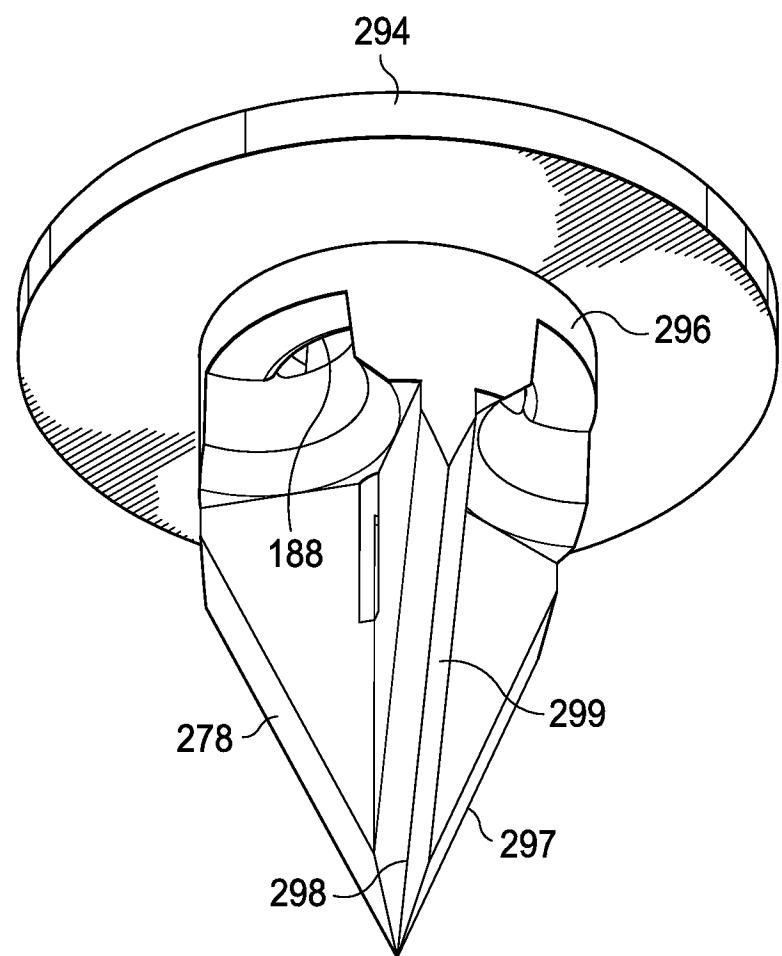


FIG. 8

7/9

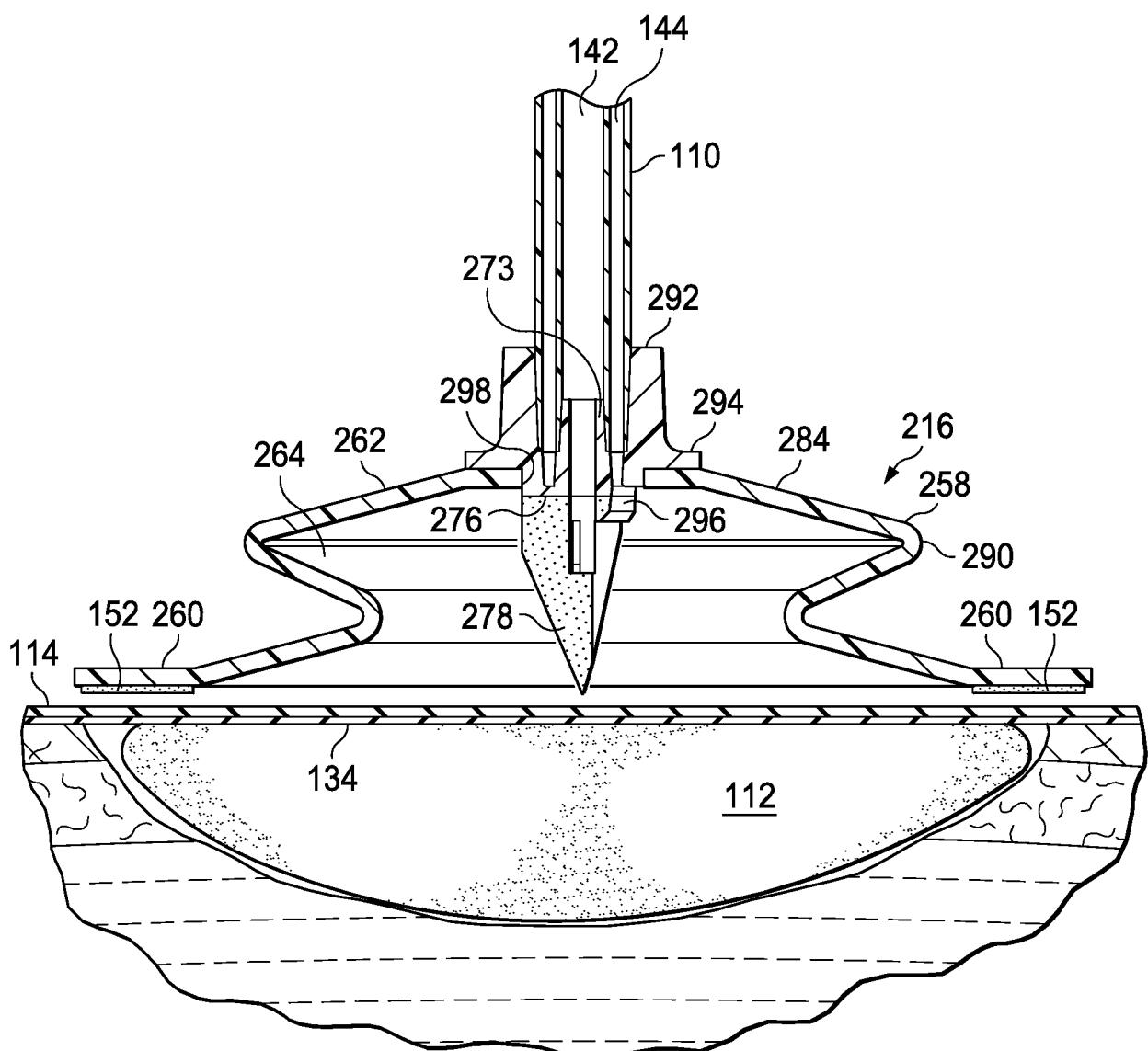


FIG. 9A

8/9

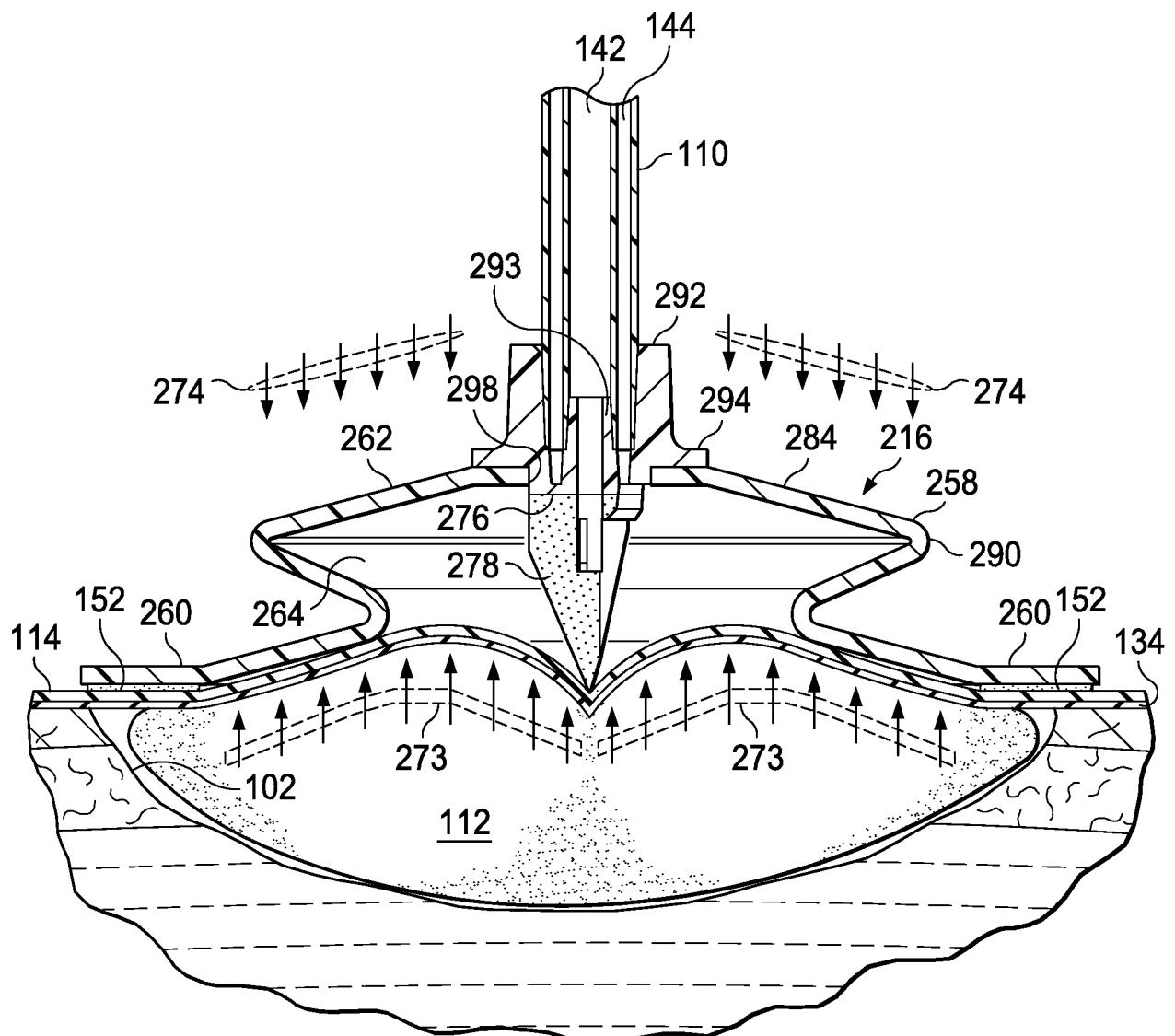


FIG. 9B

9/9

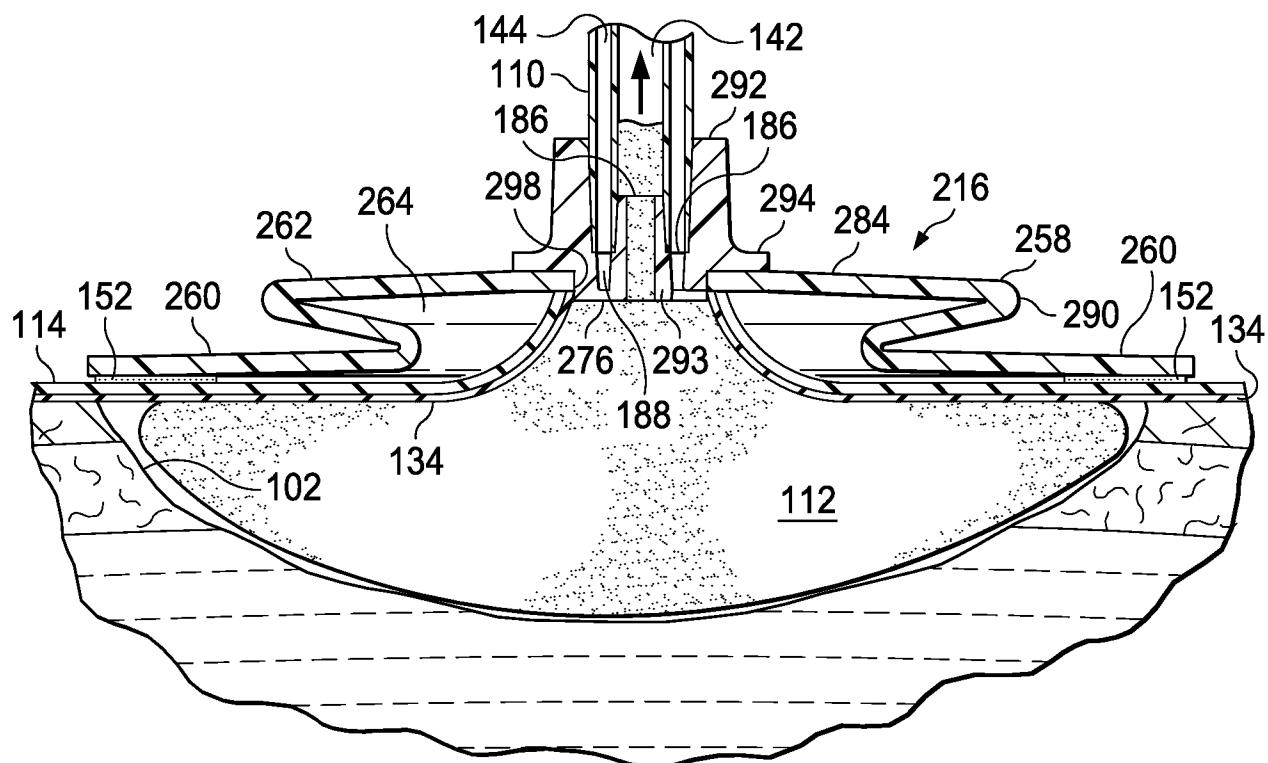


FIG. 9C

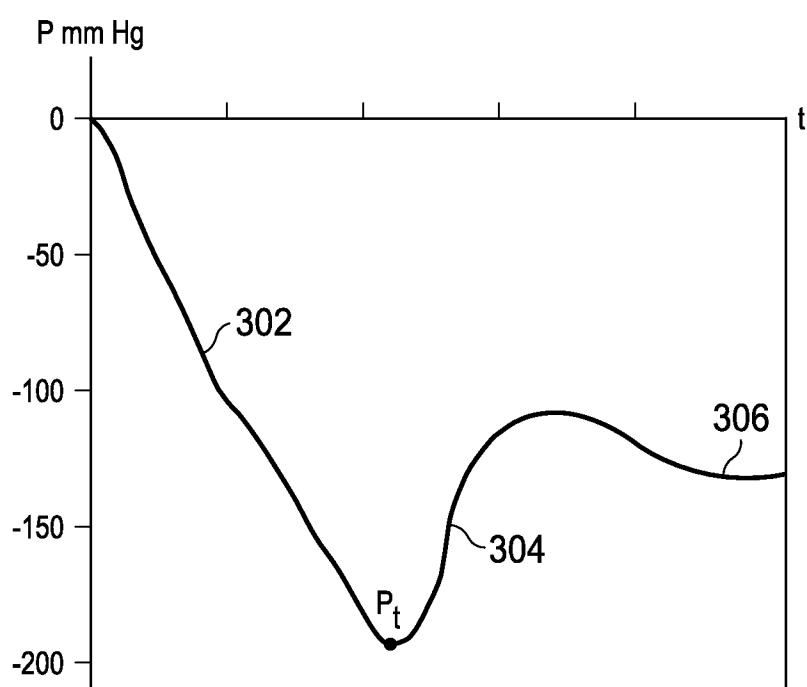


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/047736

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/00 A61F15/02
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 2009/070905 A1 (MEDELA HOLDING AG [CH]; LARSSON MICHAEL [CH]) 11 June 2009 (2009-06-11)</p> <p>page 8, line 11 - line 16 page 9, line 7 - line 27; figure 1</p> <p>-----</p> <p>WO 2010/094957 A1 (SMITH & NEPHEW [GB]; BANNISTER NEILL [GB]; HARTWELL EDWARD YERBURY [GB] 26 August 2010 (2010-08-26)</p> <p>page 8, line 2 - line 4 page 9, paragraph 1; figures 1,2,4,5b</p> <p>-----</p> <p>-/-</p>	1-7, 10-16, 19-28, 30-33, 36-41
X		1-7, 10-16, 19-28, 30-33, 36-41

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 October 2012	26/10/2012

Name and mailing address of the ISA/
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Lakkis, Angeliki

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/047736

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.: 42 because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2012/047736

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 03/073970 A1 (HILL ROM SERVICES INC [US]; LOCKWOOD JEFFREY S [US]; PETROSENKO ROBERT) 12 September 2003 (2003-09-12)</p> <p>page 11, line 29 - page 12, line 5 page 13, line 14 - line 21; figure 7 -----</p>	1-7, 10-16, 19-28, 30-33, 36-41
X	<p>WO 2011/087871 A2 (SMITH & NEPHEW INC [US]; ALBERT SEAN [US]; ARMSTRONG ED [US]; BEAUDOIN) 21 July 2011 (2011-07-21)</p> <p>paragraphs [0148], [0149]; figures 13a,b paragraph [0177]; figure 22a paragraph [0188]; figure 30a paragraph [0204]; figures 43a,b paragraph [0211]; figures 49a,b -----</p>	1-7, 10-16, 19-28, 30-33, 36-41

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2012/047736

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
WO 2009070905	A1 11-06-2009	EP 2214750	A1	11-08-2010	
		US 2010228206	A1	09-09-2010	
		WO 2009070905	A1	11-06-2009	
<hr/>					
WO 2010094957	A1 26-08-2010	AU 2010215262	A1	01-09-2011	
		CA 2752758	A1	26-08-2010	
		CN 102405068	A	04-04-2012	
		EP 2398526	A1	28-12-2011	
		JP 2012517875	A	09-08-2012	
		US 2012143156	A1	07-06-2012	
		WO 2010094957	A1	26-08-2010	
<hr/>					
WO 03073970	A1 12-09-2003	AT 526918	T	15-10-2011	
		AU 2002360757	A1	16-09-2003	
		CA 2477674	A1	12-09-2003	
		EP 1487389	A1	22-12-2004	
		US 2005085795	A1	21-04-2005	
		WO 03073970	A1	12-09-2003	
<hr/>					
WO 2011087871	A2 21-07-2011	AU 2010341491	A1	05-07-2012	
		CA 2785388	A1	21-07-2011	
		EP 2515961	A2	31-10-2012	
		US 2012116334	A1	10-05-2012	
		WO 2011087871	A2	21-07-2011	
<hr/>					

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 42

Re Item III.

Claim 42: According to Rule 6.2(a) PCT claims shall not, except where absolutely necessary, rely, in respect of the technical features of the invention, on references to the description or drawings. However, in the present case, it is apparently possible to define the subject-matter claimed in technical terms, see claims 1-41. Consequently, claim 42 has not been searched and no written opinion can be given.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.